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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Juha Voipio

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06/23/2008

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Suite 500

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EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT

PAPER NUMBER

3766

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/727,511	Applicant(s) VOIPO ET AL.	
	Examiner DEBORAH MALAMUD	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 7 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 April 2008 has been entered.
2. Claims 8-13 are cancelled; claims 1-7 are pending.

Claim Objections

3. In view of the amendments to the claims received 23 April 2008, the examiner withdraws the objection to claim 1.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-3 and 5-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. The amended subject matter, "wherein regulation of said at least one parameter is started in a state where the parameter is at a normal or unchanged level of the patient," is not described in the disclosure. The Applicant (page 5, "Remarks") points to paragraphs 0018 and 0036 as containing support for this limitation. The Examiner quotes the relevant passages below:

(par. 0018) "For the purposes of the invention, the term "regulating" refers to adjusting the intensity of the stimulation by amending any stimulation parameter, such as current, voltage, frequency, pulse width, on time, or off-time, as a response to the changes in the physiological parameters listed above. For example, when the respiratory parameter to be monitored is EtCO₂, the vagal stimulus is increased until a sufficient stimulus-induced fall in EtCO₂ is observed, or when the respiratory parameter to be monitored is RF, the vagal stimulus is increased until a sufficient increase in RF is observed. The adjustment values thus obtained can be the desired adjustment level or reference level, on the basis of which the final level will be selected. For the purposes of the invention the term "stimulation intensity" refers to stimulation parameters, such as the current or voltage used, frequency intensity, pulse width, duration of stimulation period, and duration of silent periods."

(par. 0036) "The stimulation parameter or parameters, such as current, pulse duration or any parameter that affects the effectiveness of vagus nerve stimulation, are initially adjusted to a low level. While monitoring, for example, EtCO₂, preferably during sleep for easy elimination of conscious control of respiration, the stimulus parameter value or values are increased stepwise during intervals between individual stimulation periods. For example, current is increased in steps of 0.5 mA. This procedure is continued until a change in one or more respiration parameters, such as EtCO₂, respiration rate, respiration frequency, respiration amplitude, or any parameter reflecting respiration or acid base status, is observed. For example, if EtCO₂ is being monitored, this approach provides the threshold value in the stimulation parameter, such as current as one example, for lowering of EtCO₂. After this the stimulation parameter value or values may be increased in steps to find parameter values for more pronounced or a saturating effect on the physiological parameter or parameters that are being monitored. The obtained stimulation parameter values serve as reference values, such as stimulation threshold and saturating stimulation, for adjusting the vagus nerve stimulation to produce the stimulation effectiveness that gives the desired therapeutical effect."

6. As is seen, there is no mention of where the stimulation is initially set, only that it is at a "low level." There is no mention, in these paragraphs or elsewhere in the

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Specification to support the idea that these parameters are at a "normal or unchanged level of the patient," or even what this limitation entails. That is, since step b) of claim 1 requires "regulating the stimulation intensity of the central nervous system affecting vagal nerve stimulation *in response* to [the] at least one parameter [selected from respiratory parameters and physiological acid-base parameters]," it is clear that it is not the "at least one parameter" that is being regulated, but the stimulation intensity. There is no mention that the "stimulation intensity" is at a "normal or unchanged level of the patient." For that matter, though the Specification does state that the level of the respiratory (or physiological acid-base parameter) must change in order to change the stimulation intensity to change, it is not explicitly stated that the initial value should be considered "normal."

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3 and 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons stated above, it is unclear whether it is the parameter (respiratory or physiological acid-base) or the stimulation intensity which is at the "normal or unchanged level of the patient."

Response to Arguments

9. Applicant's arguments filed 23 April 2008 have been fully considered but they are not persuasive. The essence of the Applicant's arguments appears to pertain to the amended subject matter. For the reasons stated above, the amended subject matter is unclear, and furthermore, not supported by the Specification. In addition, the Examiner considers both the VNS stimulation of Zabara in response to respiratory indicators of epilepsy, and the nervous system regulation of respiratory indicators of apnea disclosed in King, to constitute monitoring at least one parameter which correlates to the VNS intensity. Stimulation increases automatically in response to a change in respiratory parameters; this is a correlation between VNS intensity and respiratory parameters.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Zabara et al (U.S. 4,702,254). Zabara discloses (col. 5, lines 33-35; lines 49-54) a pulse generator (10) and its associated parts preferably fully implanted, and provided with means (12,

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14 and 16) for “varying the various current parameters of the pulse signal. The desired parameters are chosen by applying the electrodes (22 and 24) to the vagus nerve and varying the current parameters until the desired clinical effect is produced.” The examiner considers this to be adjusting the central nervous system affecting vagal nerve stimulation (VNS) signal induced by a stimulus generator implanted in a patient in need of vagal nerve stimulation. Zabara further discloses (col. 6, lines 40-60) a sensor-feedback system to block an epileptic seizure automatically using the implantable system. The sensor-feedback system uses, for example, sensed respiratory changes. The examiner considers this to be monitoring respiratory parameters that correlate to the VNS intensity and regulating the stimulation intensity of the central nervous system affecting vagal nerve stimulation in response to the respiratory stimulation in order to affect the brain. It is to be noted that epileptic seizures are considered to be abnormal brain-related conditions.

12. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al (U.S. 2004/0210261). King discloses (par. 0005) “techniques for treating effects of sleep apnea with neurostimulation. An implantable medical device delivers neurostimulation to one or more predetermined locations on or within a patient in order to treat effects of sleep apnea, e.g., by modulating autonomic nervous activity. Delivery of neurostimulation at predetermined locations can decrease sympathetic nervous activity and/or increase parasympathetic nervous activity, countering the increased intrinsic sympathetic activity associated with apnea-arousal cycles.” The implantable

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medical device delivers (par. 0006) neurostimulation to peripheral nerves, such as the vagus nerve. The examiner considers this to be treating an abnormal brain-related conditions by adjusting the central nervous system affecting VNS signal induced by a stimulus generator implanted in a patient in need of vagal nerve stimulation. It is to be noted that King also discloses (par. 0003) treatment of central sleep apnea (CSA), which is a “neurological condition causing cessation of substantially all respiratory effort during sleep. One common form of central sleep apnea, commonly known as Cheyne-Stokes respiration (CSR), is characterized by a breathing pattern that begins shallow and infrequent and then increases gradually to become abnormally deep and rapid, before fading away completely for a brief period. Breathing may stop altogether for an extended time period, before the next cycle of shallow breathing begins.” In one embodiment, IMD (14; par. 0032; Figure 1) “identifies apnea, or identifies the arousal resulting from apnea, and stimulates spinal cord (20) in response to the identification. Lead (14B) includes a sensor 26 that detects a physiological parameter of patient (12) associated with sleep apnea or arousal. IMD identifies apnea or arousal based on the signal conducted from sensor (26) through lead (16B).” Sensor (26) can detect apnea (par. 0034) “based on respiration of patient as detected via changes in the thoracic impedance. In such embodiments, IMD may monitor frequency, depth, pattern, and variability of respiration. Further, in such embodiments, IMD may detect Cheyne-Stokes rhythm (CSR), or may detect cessation of respiration.” The examiner considers this to be monitoring respiratory parameters that correlate to the VNS intensity and regulating

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the stimulation intensity of the central nervous system affecting vagal nerve stimulation in response to the respiratory stimulation in order to affect the brain.

13. Regarding claims 2 and 5, King discloses (par. 0049) an activity monitor (46) that provides information indicating the activity of the patient. Activity can be determined “based on below-threshold heart rate or respiration rate values.” The examiner considers this to be monitoring the respiration frequency or respiration rate of the patient.

14. Regarding claim 3, King discloses (par. 0035) an embodiment in which “sensor (26) takes the form of an optical or electrochemical sensor to detect the concentration of a gas within the blood. In such embodiments, sensor generates a signal as a function of the concentration of one or both of oxygen and carbon dioxide in the blood of patient. In such embodiments, IMD detects apnea based on a decreased concentration of oxygen and/or an increased concentration of carbon dioxide in the blood of patient.” The examiner considers this to be monitoring the CO₂ content.

Claim Rejections - 35 USC § 103

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zabara et al (U.S. 4,702,254) or King et al (U.S. 2004/0210261). Zabara and King disclose the claimed invention but do not disclose expressly the monitoring the respiratory parameter with a capnograph. It would have been an obvious matter of design choice to a person

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of ordinary skill in the art to modify the monitoring of the respiratory parameter as taught by Zabara or King, with the capnograph, because the applicant has not disclosed the use of a capnograph provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the lead-attached sensors as taught by Zabara and King, because these sensors are able to gather respiratory data in order to affect stimulation of the patient, as claimed by the applicant. Therefore, it would have been an obvious matter of design choice to modify King and Zabara to obtain the invention as specified in the claim.

Allowable Subject Matter

17. Claims 4 and 7 are allowed.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/
Examiner, Art Unit 3766